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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/802,166

03/17/2004

James Robert Schwartz

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EXAMINER

ARNOLD, ERNST V

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/802,166	Applicant(s) SCHWARTZ ET AL.	
	Examiner ERNST V. ARNOLD	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 7-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 7-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/10/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/10/08 has been entered.

Claims 2, 5 and 6 have been cancelled. Claims 1, 3, 4 and 7-25 are under examination.

Comment: The Examiner notes terminal disclaimers filed in copending applications 10/392,422; 11/216,520; 10742,557 and 11/100,648 over the instant application. To keep the record clear a non-statutory obviousness type double patenting rejection was made over copending application 10/803,126 in the office action filed on 11/30/05 but withdrawn in the office action filed on 08/10/2006. Upon further consideration, the empirical limitations recited (zinc lability of greater than about 15% and augmentation factor of greater than 1) in the applications are merely recitations of properties inherent in the same claimed material which is basic zinc carbonate. Therefore, the Examiner is reinstating the non-statutory obviousness type double patenting rejection below.

Withdrawn rejections:

Applicant's amendments and arguments filed 4/10/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

Information Disclosure Statement

Foreign references have been considered to the extent that an English language abstract or equivalent has been provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 recites that the surfactant with an anionic functional group (hence anionic surfactant) is about 1% to about 50% of the total composition. However, claim 1 limits the amount of surfactant to about 10% to about 50%. Correction is required.

Claim Rejections - 35 USC § 112

Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 12 and 13 recite: “greater than about”. Either the limitation is greater or the limitation is about. ‘Greater’ provides a static fixed point while ‘about’ provides a dynamic point. Thus it is unclear if the limitation is greater than X or about X.

Claim Rejections - 35 USC § 102

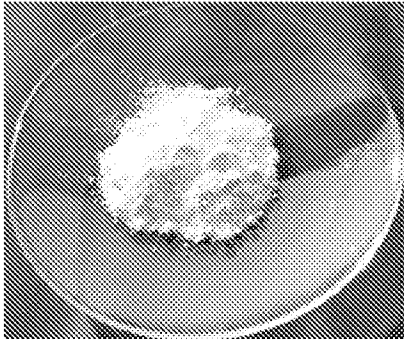
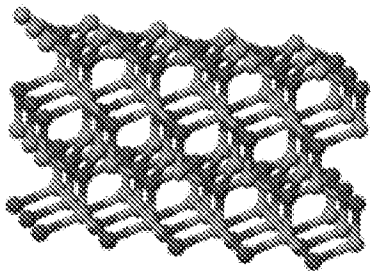
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 7-13, and 18-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gavin et al. (WO 01/00151) as evidenced by the Wikipedia Zinc Oxide.

Gavin et al. disclose a topical anti-dandruff composition for treating microbes comprising from 0.001 to 10% zinc pyrithione; from 0.001 to about 10% of a zinc salt and an anionic deterative surfactant (about 5 to about 50% by weight) for a topical carrier (Page 8, lines 10-15 and Claim 1). The zinc salt can be but is not limited to, for example, zinc oxide (page 6, lines 1-6 and Claim 6). From Wikipedia, zinc oxide is shown to clearly have a layered crystal structure reproduced below for Applicant's benefit:

Zinc Oxide	
	
	
Other names	Zinc white, calamine Zincum oxydatum
Identifiers	
CAS number	[1314-13-2]
Properties	
Molecular formula	ZnO

The ratio of surfactant to zinc containing layered material can be greater than or equal to 2 to 1. In this way, instant claims 1, 3, 4, 7 and 8 are anticipated. Since zinc oxide is a zinc layered material it would inherently have the same relative zinc lability of greater than about 15% to greater than about 20% and to greater than about 25% and thus meet the limitations of instant claims 1, 12 and 13. Please note that “relative zinc lability” is a made up in-house feature by Applicant. The pH of the compositions ranges from about 2 to about 10 and most preferably from about 5.5 to about 7.5 thus within the scope of instant claims 9-11 (Page 7, lines 7-9). The addition of cationic deposition polymers (instant claim 18) is anticipated (Page 20, lines 30-34-

page 25, line 30). The addition of conditioning agents (instant claim 19) is anticipated (Page 35, line 12- page 47, line 16). Suspending or thickening agents are anticipated and crystalline suspending agents are preferred thus reading on instant claims 20-22 (Page 18, line 27-page 20, line 28) Methods pertaining to treating microbial infections preferably related to dandruff and treating athlete's foot, a contagious fungal infection, are provided hence anticipating instant claims 23-25 (Claim 9).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 7, 8-13, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiese (US 5,227,156) as evidenced by the Wikipedia Zinc Oxide.

Wiese discloses compositions comprising up to about 40% surfactants (anionic, nonionic, amphoteric and zwitterionic); from about 0.1% to about 2% zinc pyrithione; from about 0.001% to about 1% of zinc oxide (claim 1). The evidence from Wikipedia zinc oxide is presented above and is hereby incorporated by reference. The ratio of surfactant to zinc containing layered material can be greater than or equal to 2 to 1. Since zinc oxide is a zinc layered material it would inherently have the same relative zinc lability of greater than about 15% to greater than about 20% and to greater than about 25% and thus meet the limitations of instant claims 1, 3, 4, 7, 8, 12 and 13. Wiese discloses that the pH control agents can be added such that the

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composition has a neutral to slightly acidic pH which anticipates instant claims 9-11. Wiese disclose in claim 9, a composition comprising a suspending agent (magnesium aluminum silicate/hydroxypropyl methyl cellulose (polymeric suspending agent) thus reading on instant claims 20 and 21.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 4 and 7-25 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin et al. (WO 01/00151) in view of Iwai et al. (EP 1145707A1) or Bhat et al. (WO 96/25913).

Applicant claims a composition comprising a zinc-containing layered material, a surfactant and pyrithione and methods of treating microbial infections and dandruff.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Gavin et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Iwai et al. teach compositions for external use comprising: 0.01-20 wt% of a zinc compound, such as basic zinc carbonate; 0.01-20 wt% of a thiol compound; and an anionic surfactant (Claims 1, 2, 4, 6 and 7 and page 8 lines 4 and 46 bridging page 9 line 9, for example). It is the Examiner's position that the basic zinc carbonate taught by Iwai et al. would have the same level of zinc lability as instantly claimed (claims 1, 12 and 13) in the absence of evidence to the contrary. Iwai et al. teach adding cationic surfactants (page 9, lines 4-9). Iwai et al. teach adding thickeners (suspending agents) such as gelatin, guar gum and methyl cellulose (page 9, lines 55-58). Iwai et al. teach the addition of various oils (conditioning agents) to the composition (page 8, lines 5-45).

Bhat et al. teach personal care product compositions comprising a surfactant and monophasic zinc hydroxycarbonate in an amount of 0.1-20 % by weight (Claims 1 and 2). The structure of the zinc compound is $\text{Zn}_5(\text{OH})_6(\text{CO}_3)_2 \cdot \text{X H}_2\text{O}$ where X varies between 0 and 4 (Page 6, lines 23-27). When $\text{X}=0$ then the same formula for basic zinc carbonate as disclosed by Applicant is taught (see instant specification page 6, line 6). It is the Examiner's position that the basic zinc carbonate taught by Bhat et al. would have the same level of zinc lability as instantly claimed (claims 1, 12 and 13) in the absence of evidence to the contrary. Bhat et al. teach the surfactant can be sodium lauryl sulphate, an anionic surfactant, in the amount of 2.5% (Page 12, line 10).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. Gavin et al. do not expressly teach a composition comprising as the zinc salt basic zinc carbonate. This deficiency in Gavin et al. is cured by the teachings of Iwai et al. or Bhat et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add basic zinc carbonate, as suggested by Iwai et al. or Bhat et al., to the composition of Gavin et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Gavin et al. suggest adding zinc salts to the composition but not specifically basic zinc carbonate and Iwai et al. or Bhat et al. cure this deficiency by teaching that basic zinc carbonate is suitable for external compositions. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

One of ordinary skill in the art would have been motivated to do this because Iwai et al. suggest the composition is useful for external use but not for those methods instantly claimed and Gavin et al. cure this deficiency by providing the teaching on the types of methods such a composition is useful for.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 3, 4, 7-17 and 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8, 9, 11, 12, 14-17, 21 and 23-25 of copending Application No. 10/803126. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses methods of treating microbial infections, fungal infections and dandruff with a composition comprising from about 0.01% to about 5% of a polyvalent metal salt of pyrrithione (zinc pyrrithione) and from about 0.001% to about 10% of a zinc layered material basic zinc carbonate. The copending application teaches personal care compositions such as shampoo and soaps.

The copending application does not expressly disclose adding from about 10 to 50% of the total composition of anionic surfactants to provide a ratio of surfactant to zinc layered material of greater than or equal to 2:1, pH greater than 6.5 or from about 6.8 to about 9.5 and relative zinc lability.

However, the open language of the copending application allows for the addition of anionic functional group surfactants to shampoo and soaps compositions and it is within the skill of one of ordinary skill in the art to optimize the amount of surfactant in the composition to produce the desired result and produce the instantly claimed ratio. Measurement of pH is routine in solution formulation and merely judicious selection of components to arrive at the instantly claimed pH. Relative zinc lability is intrinsic in the basic zinc carbonate.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 1, 3, 4, 7-22 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 8-12, 16-32, and 34-39 of copending Application No. 11/602770. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions, shampoo and methods of treating dandruff with an effective amount of a particulate zinc material (such as basic zinc carbonate); 0.01-5% zinc pyrithione, 1-50% anionic surfactants. The copending application discloses cationic deposition polymers, conditioning agents, suspending agents, pH ranges, relative zinc labilities and various surfactants.

The copending application does not expressly teach the amount of zinc layered material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1.

However, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1, 3, 4, 7-22 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 13-130, 35 and 37-40 of copending Application No. 11/890684. Although the conflicting claims are not identical,

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they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions and methods for treating dandruff comprising a particulate zinc material (basic zinc carbonate); 0.01 to about 5% zinc pyrithione; 1% to about 50% anionic surfactant; pH; relative zinc lability; cationic polymer; conditioning agent; and suspending agent.

The copending application does not expressly teach the amount of zinc layered material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1.

However, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1, 3, 4, and 7-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 11-27 and 33-46 of copending Application No. 11/899106. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions and methods for treating dandruff, fungal and microbial infections comprising a 0.001% to about 10% zinc containing material (basic zinc carbonate); 0.01 to about 5% zinc pyrithione; 5% to about 50% anionic surfactant; pH is greater than about 7; relative zinc lability; cationic polymer; conditioning agent; and suspending agent.

The copending application does not expressly teach a ratio of surfactant to zinc layered material of greater than or equal to 2:1.

However, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1, 3, 4, 7, 8, 12, 13, and 15-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-7 of copending Application No. 12/029150 in view of Gavin et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions comprising a zinc containing layered material (basic zinc carbonate); anionic surfactant; and relative zinc lability. The copending application does not expressly teach adding zinc pyrithione or the amount of zinc layered material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1.

Gavin et al. teach zinc pyrithione in personal care compositions for treating microbes as discussed above.

However, the open language of the copending application allows for the addition of other ingredients such as zinc pyrithione as taught by Gavin et al. With respect to the amounts of

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ingredients, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST V. ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 6:15-3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/
Examiner, Art Unit 1616